

October 23, 2000

URGENT

NATIONAL

The Honorable Jane Henney Commissioner Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857

Food

PROCESSORS

Dear Commissioner:

ASSOCIATION

John R. Cady

President and

Chief Executive Officer

We understand that the Food and Drug Administration (FDA) is considering the issuance of new consumer guidance on methylmercury in fish as early as November 20, 2000. We also understand that the guidance will be based on the Faroe Islands study, one of the studies considered in the NAS Committee report on the Toxicological Effects of Methylmercury, published in July of this year. This action could have an irreversible impact on American dietary habits, profoundly affecting consumers and producers of seafood and resulting in significant segments of the population turning away from the proven health benefits of fish consumption. It would be a serious disservice to public health to base any consumer guidance on the Faroe Islands study, a study that bears no relationship to consumption patterns of fish consumers in the United States.

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A number of eminent toxicologists and risk assessors, including those at the Agency for Toxic Substances and Disease Registry (ATSDR) and at the FDA itself, have raised serious questions regarding the use of the Faroè Islands study as the basis for consumer guidance on fish consumption in the United States. Questions have been raised regarding the episodic nature of the methylmercury, PCBs and other persistent organic pollutants (POPs) intake by the Faroe Islands people. Questions have also been raised regarding the method used in this study to calculate the levels of PCBs consumed through eating whale meat and blubber and the confounding role of POPs and PCBs (the PCBs levels alone being 70 times higher than the EPA recommended level for PCBs) in efforts to assess the effects of methylmercury on this population. In fact, subsequent to release of the NAS Committee report, Dr. D.C. Bellinger of the Harvard Medical School and a member of the NAS Committee, co-authored a WHO report (Geneva, 2000) which stated in relation to the Faroe Islands study that, "the confounding role of PCBs and persistent organic pollutants should be reassessed in order to determine the role of methylmercury in the adverse effects reported in the study." Given that the NAS Committee report itself stated that "The potential for confounding by PCB exposure is of some concern for the Faroe Islands study," it would appear that much more work needs to be done before a new consumption advisory is discussed by FDA.

WASHINGTON, DC DUBLIN, CA SEATTLE, WA

The agencies have continued to fund the Seychelles study, which we understand is near completion and now includes for the first time a direct comparison of outcomes from identical test batteries in the Faroe Islands study. We believe the Seychelles

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study to be a definitive work on fish consumption that would most closely apply to the America consumption pattern and all stakeholders should have the advantage of the study results before a nev FDA consumption advisory is discussed. Furthermore, the beneficial health effects of consuming fish have been acknowledged not only by our own government with the recent publication of HHS and USDA's 2000 Dietary Guidelines for Americans and USDA's two Food Guide Pyramids (Americans and Children) but also by the American Heart Association in their recently revised dietary guidelines. It is critical that consumers not receive conflicting messages from government agencies and credible health and medical groups. Consumer advice must be clear, consistent and based on the totality of sound scientific evidence in order to avoid confusion.

We would be grateful for your urgent clarification as to how you intend to reach a scientific consensus on this important issue before the FDA takes precipitate action. It would be a great disservice to public health to proceed with a new advisory using disputed scientific data which would result in significant sections of the population being confused and denied the health benefits of fish consumption.

There can be no rush to judgment in 30 to 60 days on this important issue without having all of the pertinent scientific data available and before the surrounding questions on the entire issue of a new consumption advisory are addressed. The concerns and questions posed by reputable scientists on the NAS Committee report and its use of the Faroe Islands study to affect U.S. public health policy on fish consumption dictate that an FDA pronouncement not occur for a minimum of seven to eight months so all stakeholders can scientifically address the areas of concern we have cited. The Seychelles study results must be included in the total scientific analysis of methylmercury and fish.

We hope we can discuss this letter immediately upon your return to your office.

Yours sincerely.

John R. Cady

President and CEO

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